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| 09/614,264      | 07/12/2000  | Peter Lohse          | 50036/028002        | 2135             |

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Karen L Elbing PhD  
Clark & Elbing LLP  
176 Federal Street  
Boston, MA 02110

EXAMINER

LU, FRANK WEI MIN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1634

DATE MAILED: 03/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/614,264

Applicant(s)

LOHSE ET AL.

Examiner

Frank Lu

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 14-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-16 and 19-31 is/are rejected.
- 7) ☒ Claim(s) 17 and 18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 July 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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**DETAILED ACTION**

***Election/Restriction***

1. Applicant's election without traverse of Group II, claims 14-31 in Paper No. 7 is acknowledged.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention

Claim 25 is rejected as vague and indefinite over the phrase "wherein said first functional group has a reactivity orthogonal to the reactivity of said second functional group" because it is unclear what it intended. For example, does this phrase mean that said first functional group has a reactivity that is different from the reactivity of said second functional group or mean something else?

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. Claims 14-16, 19-26, and 28-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Yanagawa *et al.*, (US patent No. 6,228,994 B1, filed on November 13, 1998).

Yanagawa *et al.*, teach labeled protein and its producing method.

Regarding claim 14, Yanagawa *et al.*, teach a method for analyzing a function of a gene.

This method comprised three steps: (1) adding a nucleic acid containing the gene to a cell-free protein synthesis system as a template; (2) carrying out protein synthesis in the presence of a labeling compound such as fluorpur or fluorthiopur (only binding to protein, not RNA) to obtain a protein having the labeling compound attached to the C-terminal of the protein wherein the labeling compound was present at a concentration effective for the labeling compound to bind to the C-terminal of the synthesized protein; and (3) analyzing a function of the labeled protein (for example, see columns 1, 2, and 10). Although Yanagawa *et al.*, did not directly show to form a stalled translation complex recited in step (b) of the claim, in the absence of convincing evidence to the contrary, a translation complex after the translation was terminated and before peptide was released could be considered as a stalled translation complex. Note the specification did not have a definition for "a stalled translation complex".

Regarding claims 15 and 16, the fluorescent tag was attached to the 5'-hydroxy group of a puromycin through a phosphate group (for example, see column 5 and Figure 2).

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Regarding claim 19, the vector sequence in plasmid (pT-Trx) could be considered as a DNA oligomer that was covalently linked to 3' end of said nucleic acid sequence encoding said protein (thioredoxin with a coding region) (see column 9) since the bond connected the bases in the nucleic acid was 3, 5-phosphodiester bond.

Regarding claims 20-24, 26, and 28, since the labeling compound (tag) could be biotin or fluorescein series (see column 3), the tag could be considered as a small molecule and a functional group recited in claims 20-22 and 24. Biotin tag could be considered as a tether for attachment to a solid support recited in claim 26 or one member of a specific binding pair recited in claim 28 since it could bind to avidin or streptavidin.

Regarding claim 25, the first function group of said protein could be considered as any amino acid in said protein that had a different reactivity from said tag (second functional group such as biotin).

Regarding claim 29, fluorpur or fluorthiopur tag (see Figure 2) could be considered as a phenyl diboronic acid derivative.

Regarding claims 30 and 31, Yanagawa *et al.*, taught puromycin derivatives such as rCpPur (II) or dCpPur (III) or dUpPur (IV) comprising a nucleotide sequence positioned between the tag and puromycin (see Figure 1 and column 10).

Therefore, Yanagawa *et al.*, teach all limitations recited in claims 14-16, 19-26, and 28-31.

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***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yanagawa *et al.*, (1998) as applied to claims 14-16, 19-26, and 28-31 above, and further in view of Schatz *et al.*, (US Patent No., 5,723,584, published on March 3, 1998).

The teachings of Yanagawa *et al.*, have been summarized previously, *supra*.

Yanagawa *et al.*, did not disclose to attach the tag of a protein having a puromycin label to beads recited in claim 27.

Schatz *et al.*, teach to use streptavidin-coated beads for a wide variety of purposes such as purification of biotinylation peptides (see column 13).

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Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to attach the tag of a protein having a puromycin label to streptavidin-coated beads in view of the reference of Schatz *et al.*. One having ordinary skill in the art would have been motivated to modify the method of Yanagawa *et al.*, and combine above methods together in order to purify the protein with a puromycin modification using streptavidin-coated beads and further analyze the function of the modified protein (see Yanagawa *et al.*, column 2). One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to purify a protein with a puromycin modification using streptavidin-coated beads since this method provided a convenient, efficient, economical way to separate the modified and unmodified protein.

### ***Conclusion***

8. Claims 17 and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
9. No claim is allowed.
10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94

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(December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 308-0196.



Frank Lu  
March 6, 2002